ABSTRACTS

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Conformable stent graft for the treatment of acute, complicated type B dissection: Multicenter clinical trial

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Objective: The treatment of acute, complicated type B aortic dissection has evolved in the past several decades. Thoracic endovascular aortic repair when anatomy is suitable, has been regarded as the preferable treatment to seal the primary entry tear, redirect and re-establish adequate true lumen flow, and thereby promote aortic remodeling. This study was designed to determine the safety and efficacy of a conformable thoracic endoprosthesis device for patients with acute, complicated type B aortic dissection, defined as malperfusion or rupture or both.

Methods: Between January 2010 and January 2012, 50 patients with complicated type B aortic dissection from 26 sites in the United States were included in this prospective, multicenter, nonrandomized single-arm study. The primary safety end point was all-cause mortality through 30 days after treatment, and the primary efficacy end point was exclusion of the primary entry tear (Core Laboratory adjudicated) at 1-month follow-up. Secondary end points included false lumen thrombosis, dissection-based reintervention rate, and aortic rupture.

Results: All device implants were successfully completed. Six patients (12%) required additional device implantations $\leq$1 year from the index procedure. There was no conversion to open repair at 1 year. Exclusion of the primary entry tear at 30 days occurred in 97.5% of patients. All-cause mortality through 30 days was 8%. Survival was 88% at 1 year and 85% at 2 years. At 1 year after treatment, 35.1% of patients had experienced a decrease of $\geq$5 mm in overall diameter in the treated segment of the aorta. From pretreatment to the 36-month follow-up, the average minimum true lumen area increased by 206.3 mm^2, and the average maximum false lumen area decreased by 313.4 mm^2. The 30-day stroke rate was 18%; none were fatal, and one permanent deficit occurred. Four patients (8%) experienced spinal cord ischemia of any severity but without any permanent or significant deficits. New aortic dissection (3 retrograde, 2 de novo) occurred in five patients (10%). The secondary intervention rate was 18%.

Conclusions: Treatment with the conformable thoracic endovascular aortic repair device produced favorable perioperative and intermediate level clinical and anatomic outcomes. In particular, an operative mortality of 8% in this cohort is comparable to that noted in a Society for Vascular Surgery objective performance criteria publication. Late survival in our cohort compares favorably with historical data referable to complicated type B dissection.

Multicenter Nellix EndoVascular Aneurysm Sealing system experience in aneurysm sac sealing

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Objective: Despite improvements in endograft devices, operator technique, and patient selection, endovascular repair has not achieved the long-term durability of open surgical aneurysm repair. Persistent or recurrent aneurysm sac flow from failed proximal sealing, component failure, or branch vessel flow underpins a significant rate of reintervention after endovascular repair. The Nellix device (Endologix, Irvine, Calif) employs a unique design with deployment of polymer-filled EndoBags surrounding the endograft flow lumens, sealing the aneurysm sac space and potentially reducing complications from persistent sac flow. This retrospective analysis represents the initial experience in consecutive patients treated with the device in real-world practice.

Methods: This study was performed at six clinical centers in Europe and one in New Zealand during the initial period after commercialization of the Nellix device. Patients underwent evaluation with computed tomography and other imaging modalities following local standards of care. Patients were selected for treatment with Nellix and treated by each institution according to its endovascular repair protocol. Clinical and imaging end points included technical success (successful device deployment and absence of any endoleak at completion angiography), freedom from all-cause and aneurysm-related mortality, endoleak by type, limb occlusion, aneurysm rupture, and reintervention.

Results: During a 17-month period, 171 patients with abdominal aortic aneurysms were treated with the Nellix device and observed for a median of 5 months (range, 0-14 months). The 153 male and 18 female patients with mean age of 74 $\pm$ 7 years had aneurysms 61 $\pm$ 9 mm in diameter with an average infrarenal neck length of 28 $\pm$ 15 mm and

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infrarenal angulation of 37 ± 22 degrees. Technical success was achieved in all but two patients (99%); one patient had a type Ib endoleak and another had a type II endoleak. Through the last available follow-up, type Ia endoleak was observed in five patients (3%), type Ib endoleak in four patients (2%), and type II endoleak in four patients (2%). There were eight limb occlusions (5%), among which seven were evident at the 1-month follow-up visit. Aneurysm-related reinterventions were performed in 15 patients (9%). There were no aneurysm ruptures or open surgical conversions.

Conclusions: This first multicenter postmarket report of the Nellix device for infrarenal abdominal aortic aneurysm repair demonstrates satisfactory results during the initial learning phase of this new technology. The rate of aneurysm exclusion was high, and frequency of complications was low. More definitive conclusions on the value of this novel device await the results of the ongoing Nellix EVAS FORWARD Global Registry and the EVAS FORWARD investigational device exemption trial.

Performance of the Endurant stent graft in challenging anatomy

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Objective: This study aimed to compare perioperative and postoperative outcomes after endovascular repair of abdominal aortic aneurysms (AAAs) in patients with various neck morphologic features.

Methods: Data from the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) were used for the analyses. Patients were categorized into three different groups according to proximal aortic neck anatomy: regular (REG), intermediate (INT), and challenging (CHA). REG was defined as AAAs with a proximal neck ≥15 mm combined with a suprarenal angulation (α) ≤45 degrees and an infrarenal neck angulation (β) ≤60 degrees. INT was defined as AAAs with a proximal neck of 10 to 15 mm combined with α ≤45 degrees and β ≤60 degrees or with a proximal neck of >15 mm combined with α ≤60 degrees and β = 60 to 75 degrees or α = 45 to 60 degrees and β ≤75 degrees. CHA was defined as infrarenal necks that exceed at least one of the three defining factors.

Results: Overall, 925 patients (75.9%) had REG anatomy, 189 patients (15.5%) had INT anatomy, and 104 patients (8.5%) had CHA anatomy. Patient demographics and risk factors were similar. There was a significant difference in AAA diameter between the REG and CHA groups (59.4 mm vs 65.2 mm; $P < .001$). Technical success was similar among groups (REG 99.1% vs INT 99.5% vs CHA 97.1%). There were no differences in mortality or the need for secondary procedures within 30 days or at 1 year. A significantly higher rate of type I endoleaks within 30 days was seen in CHA compared with REG (adjusted odds ratio, 0.15; 95% confidence interval, 0.05-0.46) and INT (adjusted odds ratio, 0.08; 95% confidence interval, 0.01-0.70), but there was no difference at 1-year follow-up.

Conclusions: This real-world, global experience shows promising results and indicates that endovascular AAA repair with the Endurant stent graft (Medtronic Vascular, Santa Rosa, Calif) is safe and effective in patients with challenging aortic neck anatomy. However, long-term follow-up of patients is required to confirm results.

Comparison of domain-specific cognitive function after carotid endarterectomy and stenting

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Background: Observational data indicate that carotid artery stenting (CAS) is associated with higher incidence of subclinical cerebral microemboli than carotid endarterectomy (CEA). We hypothesized that CEA would be associated with superior performance on detailed domain-specific cognitive testing compared with CAS.

Methods: Patients with >80% asymptomatic carotid artery stenosis were randomized to CEA or CAS with side of stenosis balanced across condition. A robust battery of tests was used to assess the cognitive domains of attention, memory, mood, visual-spatial skills, motor ability, processing speed, and executive functioning ≤10 days preoperatively and postoperatively at 6 weeks and 6 months. Tests were administered using standardized conditions and were scored by individuals blinded to treatment allocation.

Results: Baseline cognitive performance was similar between CAS (n = 29) and CEA (n = 31) groups ($P > .05$). Relative to baseline, verbal and visual memory and attention functions substantially improved in the CAS and CEA groups at 6 months (multiple cognitive tests achieved statistical significance). Compared with CEA, cognitive processing speed (Stroop Color test: 9.0 vs 7.3, $P = .04$; and Stroop Word test: 9.0 vs 7.4, $P = .05$) was superior in the CAS group at 6 weeks. Executive functioning (phonemic verbal fluency: 10.6 vs 8.4, $P = .043$) and motor function (Grooved Pegboard of nondominant extremity: 45.7 vs 38.9, $P = .022$) were also superior in the CAS group at 6 months. Tests of attention, memory, and visual-spatial skills were similar between CAS and CEA patients at 6 weeks and 6 months.

Conclusions: Carotid revascularization improves memory and attention within the first 6 postoperative months. Compared with CEA, CAS produces improvements in cognitive processing speed, executive functioning, and motor function.

Outcomes of completion imaging for lower extremity bypass in the Vascular Quality Initiative

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Objective: The objective of this study was to determine the association of intraoperative completion imaging (CI) for lower extremity vein bypass to a below-knee target with primary patency in the Vascular Quality Initiative.
Methods: The Vascular Quality Initiative database was queried from January 2003 to October 2013 for lower extremity bypass (LEB) procedures that were elective, had an indication of occlusive disease, used a single-segment greater saphenous vein conduit, and had a below-knee target. LEBs with inflow arteries above the knee and below the knee were included. LEBs with concomitant endovascular procedures were excluded. CI was defined as completion angiography, completion duplex ultrasound, or both. The end points were primary patency at discharge and at 1 year. Multivariable analysis was performed controlling for patient demographics, comorbidities, bypass characteristics, and center.
Results: Of 14,284 LEBs that were performed during the study period, 3147 satisfied the inclusion and exclusion criteria. Of 1457 (46%) that underwent CI, 287 (20%) underwent duplex ultrasound, 1116 (77%) underwent angiography, and 54 (3.7%) underwent both duplex ultrasound and angiography. There were more patients in the CI group with a history of smoking and a bypass graft crossing the knee. There was no difference in primary patency at discharge between the two groups (CI, 93.2% vs no CI, 93.8%; $P = .52$). Of the patients who underwent CI, the discharge primary patency was 95.1% for completion duplex ultrasound vs 92.8% for completion angiography ($P = .17$). On multivariable analysis, there was no significant association of CI with discharge primary patency ($P = .69$). The 1-year primary patency was 63% in the CI group vs 68% in the no CI group ($P = .051$). The 1-year primary patency was 60% for the duplex ultrasound group vs 65% for the angiography group ($P = .61$). On multivariable analysis, there was no significant association of CI with 1-year primary patency ($P = .69$).
Conclusions: In electively performed LEBs using single-segment saphenous vein to a below-knee target artery for occlusive disease, CI does not influence primary graft patency at discharge or at 1 year.

A novel tool for three-dimensional roadmapping reduces radiation exposure and contrast agent dose in complex endovascular interventions

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Objective: The volume and complexity of endovascular procedures are increasing. Multidetector computed tomography (CT) made precise three-dimensional (3D) planning of these procedures possible, but intraoperative imaging, even with the use of modern flat-panel detectors, is limited to two dimensions. Flat detectors, however, allow C-arm cone-beam CT. This technology can be used to generate a 3D data set that can be fused with a preoperative high-resolution CT scan, thus generating a live 3D roadmap. We hypothesized that use of a novel image fusion software, VesselNavigator (Philips Healthcare, Best, The Netherlands), facilitates precise and expeditious procedures and therefore reduces radiation exposure and contrast agent dose.
Methods: A retrospective review of patients undergoing standard aortobi-iliac endovascular aneurysm repair at our institution between January 2011 and April 2014 was performed. Conventional imaging was compared with VesselNavigator-assisted imaging, and a matched analysis based on body mass index (BMI) was performed because of the dependence of radiation dose on body habitus. Outcome parameters were procedure time, fluoroscopy time, radiation, and contrast agent dose.
Results: A total of 75 patients were identified. After matching based on BMI, control and VesselNavigator groups each had 16 patients with BMI of 27.0 $\pm$ 3.6 kg/m^2 and 27.0 $\pm$ 3.6 kg/m^2, respectively (mean $\pm$ standard deviation). R^2 was 6.37 Ã 10$^{\hat{a}\text{-}\ 7}$. Radiation dose measured as air kerma was lower with VesselNavigator (1067 $\pm$ 470.4 mGy vs 1768 $\pm$ 696.2 mGy; $P = .004$). Fluoroscopy time was shorter (18.4 $\pm$ 6.8 minutes vs 26.8 $\pm$ 10.0 minutes; $P = .01$) and contrast agent dose was lower (37.4 $\pm$ 21.3 mL vs 77.3 $\pm$ 23.0 mL; $P < .001$) with VesselNavigator compared with control. Procedure time was also shorter with VesselNavigator (80.4 $\pm$ 21.2 minutes vs 110.0 $\pm$ 29.1 minutes; $P = .005$).
Conclusions: Image fusion using VesselNavigator enhances the functionality of conventional fluoroscopy in standard endovascular aneurysm repair. It reduces radiation exposure to patients and providers. It also limits the amount of contrast agent and shortens the overall procedure length. The benefit of this technology is demonstrated on this typically straightforward procedure but may be even more useful for complex procedures.